SEP - 9 2003

K031970
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510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Solutuions
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: Connie Hertel, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: June 20, 2003

Trade Name, Common Name and Classification Name:

A. Trade Name:
INFINITY MegaCare

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
System, ECG Analysis	LOS		
Computer, diagnostic, programmable	DQK	II	21CFR 870.1425

Predicate Device Identification:

K980625	Infinity MultiView WorkStation Enhanced with Diagnostic Statements (Rest ECG)
K992637	Muse Cardiovascular Information System
K974420	TraceMaster ECG Management System
K946281	Burdick Eclipse 4 Electrocardiograph

Device Description:
INFINITY MegaCare is a computer software program that allows viewing, manual editing, printing and archiving of digitized electrocardiograph records from Rest ECG devices, Exercise ECG devices, ambulance ECG devices, Holter ECG devices and the INFINITY Monitoring System.

510(k) Notification
INFINITY MegaCare

INFINITY MegaCare uses the Microsoft Windows 2000 server operating system, Microsoft IIS Web server, and Microsoft SQL Server 2000 relational database. The system consists of a software application, which is installed on a user provided IBM compatible server running the Microsoft Windows 2000 Server operation system. MegaCare utilizes the ECG analysis algorithm developed under the direction of Dr. Peter MacFarlane at the University of Glasgow and used for the INFINITY MVWS Rest ECG (K980625) and Burdick's Eclipse 4 Electrocardiograph (K946281).

Intended Use:
INFINITY MegaCare is a software application for viewing, manual editing, printing, and archiving of digitized electrocardiograph records from Rest ECG devices, Exercise ECG devices, Ambulance ECG devices, Holter ECG devices and the Infinity Monitoring System.

INFINITY MegaCare is intended to provide analysis or reanalysis of Rest ECG's and to provide preliminary data for editing and confirmation by a physician. Infinity MegaCare can provide a serial comparison of Rest ECG data to facilitate the review of current and previous Rest ECG's.

INFINITY MegaCare is designed for network compatibility to facilitate retrieval of data and to interface with other hospital information systems though HL7 protocols.

Assessment of non-clinical performance data for equivalence:
Substantially equivalent (Section S)

Assessment of clinical performance data for equivalence:
Substantially equivalent (Section T)

Biocompatability:
Not applicable

Sterilization:
Not applicable

Standards and Guidance: Section R

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2003

Siemens Medical Solutions USA, Inc.
Electromedical Systems Group, PCS
c/o Ms. Penelope H. Greco
Regulatory Submissions Manager
16 Electronics Avenue
Danvers, MA 01923

Re: K031970
Trade Name: Siemens INFINITY MegaCare
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: June 20, 2003
Received: June 26, 2003

Dear Ms. Greco:

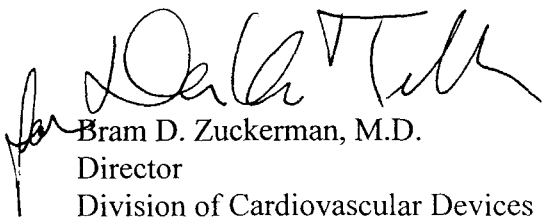
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031970

510(k) Number (if known):_____

Device Name: Siemens INFINITY MegaCare

Indications for Use:

INFINITY MegaCare is a software application for viewing, manual editing, printing, and archiving of digitized electrocardiograph records from Rest ECG devices, Exercise ECG devices, Ambulance ECG devices, Holter ECG devices and the Infinity Monitoring System.

INFINITY MegaCare is intended to provide analysis or reanalysis of Rest ECG's and to provide preliminary data for editing and confirmation by a physician. INFINITY MegaCare can provide a serial comparison of Rest ECG data to facilitate the review of current and previous Rest ECG's.

INFINITY MegaCare is designed for network compatibility to facilitate retrieval of data and to interface with other hospital information systems though HL7 protocols.

The device is intended for use in an environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The device is intended for use with all patient populations.

MRI Compatibility Statement:
The INFINITY MegaCare is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031970